

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Alastair J.T. CLEMOW et al.
Title: MODULAR FEMORAL
COMPONENT FOR A TOTAL
KNEE JOINT REPLACEMENT FOR
MINIMALLY INVASIVE
IMPLANTATION
Appl. No.: 10/532,409
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Examiner: David C. Comstock
Art Unit: 3733
Confirmation Number: 9135

PRE-APPEAL BRIEF REQUEST FOR REVIEW

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Commissioner for Patents
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Sir:

In accordance with the New **Pre-Appeal Brief Conference Pilot Program**, announced July 11, 2005, this Pre-Appeal Brief Request is being filed together with a Notice of Appeal. Consideration is respectfully requested in light of the following remarks.

REMARKS

1. **The Rejection Of Claims 23-27 Under 35 U.S.C. § 102(b) as Being Anticipated by U.S. Patent No. 6,168,629 ("Timoteo") is Improper, as Timoteo Simply Does Not Identically Disclose or Describe the Expressly Claimed Subject Matter**

Timoteo discloses a femoral component having two lateral condyles 2, 3 that form an intercondylar space 4. See Timoteo at col. 2, lines 64-67. A third condyle 9 can be fitted into the intercondylar space 4 when the posterior cruciate ligament of a patient is absent and posterior stabilization is needed. See Timoteo at col. 3, lines 9-17. On page 2 of the Office Action, the Office identifies condyles 2, 3, 9 as "segments" (a term used in the pending claims).

Independent claim 23 recites:

A method of implanting a femoral component for a total knee joint replacement on a distal end of a femur comprising the steps of:
providing a plurality of segments, each of said segments having a femoral fixation surface adapted to be positioned on a distal end of a femur and at least one assembly surface adapted to be joined to an assembly surface of an adjacent one of said segments; and
selecting segment sizes configured to position the assembly surfaces of the segments at a desired location when implanted on a distal end of a femur. [Emphasis added.]

a. Timoteo does not anticipate the step of “providing a plurality of segments” having specified structure, as recited in independent claim 23

The method of claim 23 requires the step of “providing a plurality of segments,” each of which segments includes both (a) “a femoral fixation surface adapted to be positioned on a distal end of a femur” and (b) “at least one assembly surface adapted to be joined to an assembly surface of an adjacent one of said segments.”

Timoteo unquestionably fails to teach this step of claim 23, because Timoteo does not disclose a plurality of segments that each have the specified structure. The Office relies on Timoteo’s disclosure of the three condyles 2, 3, and 9 to meet the recited step of “providing a plurality of segments.” However, the condyle 9 fails to have the specified structure, e.g., “a femoral fixation surface adapted to be positioned on a distal end of a femur,” as required by the claim.

In apparent recognition of this deficiency of Timoteo, the Office asserts on page 4 of the Office Action that “the structural limitations pertaining to the nature of the segments . . . have not been given patentable weight.” It is improper for the Office to ignore expressly recited claim limitations.

Again in apparent recognition of the deficiency of Timoteo, the Office further asserts on page 4 that the condyle 9 of Timoteo “would engage a distal end of the femur (e.g., an osteophyte).” There is no indication whatsoever in Timoteo that condyle 9 would engage an osteophyte, i.e., bone spur. Moreover, Timoteo teaches that the condyle 9 is installed so that it is removable. See Timoteo at col. 1, line 64 to col. 2, line 2; col. 2, lines 35–43. Thus, Timoteo teaches away from any femoral fixation surface used to fix the condyle 9 to the femur (or a bone spur).

Yet again in apparent recognition of the deficiency of Timoteo, the Office further asserts on page 4 that “femoral fixation surface” has not been explicitly defined by the Applicant. However, the present application at paragraph [0028] explains that “[a]t least some of the individual modules of the modular prosthesis have a femoral fixation surface that is adapted to contact the surgically prepared distal end of the femur and be attached by conventional methods such as an appropriate cement,

mechanical fastener or the like.” Additionally, paragraph [0029] distinguishes between components that have femoral fixation surfaces and those that do not, i.e., mere “spacers” (such as the condyle 9 of Timoteo). Suffice it to say that a person skilled in the art would know very well that the condyle 9 of Timoteo does not include a “femoral fixation surface” as recited in claim 23.

b. Timoteo does not anticipate the step of “selecting segment sizes,” as recited in independent claim 23

The method of claim 23 also requires the step of “selecting segment sizes configured to position the assembly surfaces of the segments at a desired location when implanted on a distal end of a femur.”

The Office fails to point to any disclosure in Timoteo of such a step. Timoteo is silent in regard to the selection of different sizes of condyles 2, 3, 9 for any purpose, and certainly fails to disclose selecting sizes such that assembly surfaces of the condyles 2, 3, 9 are at a desired location when implanted on a distal end of a femur.

The Office asserts on page 4 of the Office Action that “the segments of Timoteo inherently comprise at least one size, and such elements are selected when they are implanted.” The Office, however, fails to point to any teaching in Timoteo of (a) selecting segments based on size or (b) selecting segment sizes such that the assembly surfaces are positioned at a desired location when implanted. The Office has improperly ignored these limitations of the claim.

Dependent claims 24-27 depend directly or indirectly from independent claim 23. Consequently, they are patentable over Timoteo for at least the same reasons as claim 23.

2. The Rejection Of Claims 1-22 Under 35 U.S.C. § 103(a) as Being Unpatentable Over Timoteo is Improper

a. Timoteo does not teach or suggest a femoral component with (a) three segments that can be separately inserted through an incision and (b) a third segment with a central bearing surface on an anterior portion of the component, as recited in independent claim 1

Independent claim 1 recites:

A femoral component for a total knee joint replacement comprising,
a first, second, and third segment, each of said first and second segments having a femoral fixation surface adapted to be positioned on a distal end of a femur, each of said first, second, and third segments having at least one assembly surface adapted to be joined to an assembly surface of an adjacent one of said first, second, and third segments, said assembly surface being generally planar and arranged to be oriented generally in a plane extending in a proximal-distal direction and in an anterior-posterior direction when said femoral fixation surface is positioned on said distal end of said femur,

wherein each of the first, second and third segments is configured to be separately inserted through an incision in a person and assembled to another of the first, second, and third segments after insertion through the incision, and wherein the third segment comprises a central bearing surface on an anterior portion of said component. [Emphasis added.]

Timoteo does not teach or suggest such a femoral component that includes a first, second, and third segment “configured to be separately inserted through an incision in a person and assembled to another of the first, second, and third segments after insertion through the incision,” as recited in claim 1. Condyles 2 and 3 of Timoteo are not configured to be separately inserted through an incision because condyles 2 and 3 are formed by a single piece of the femoral component. The Office asserts that it would have been obvious to form the condyles 2 and 3 as separate components to “facilitate manufacturing,” but the Office offers no indication of how that would facilitate manufacturing and points to no recognition in the art that it would facilitate manufacturing.

Timoteo also does not teach or suggest such a femoral component, “wherein the third segment comprises a central bearing surface on an anterior portion of said component.” Such a central bearing surface of a third segment can be used, for example, to replace the natural patellofemoral bearing surface of a femur. The condyles 2, 3, 9 of Timoteo do not comprise a central bearing surface on an anterior portion of the femoral component because these condyles are located at the posterior portion of the femoral component, not the anterior portion. For instance, Timoteo discloses that condyle 9 is used to provide posterior stabilization. See Timoteo at col. 3, lines 9-17. Condyles 2 and 3 also lie in the same region as condyle 9, as shown in the figures of Timoteo. Therefore, Timoteo does not disclose a third segment, “wherein the third segment comprises a central bearing surface on an anterior portion of said component,” as recited in claim 1.

Dependent claims 2-8 and 10-20 depend directly or indirectly from independent claim 1. Consequently, they are patentable over Timoteo for at least the same reasons as claim 1.

b. Timoteo does not teach or suggest a femoral component having (a) segments each with a femoral fixation surface and (b) adjacent segments forming a bearing surface on an anterior portion, as recited in independent claim 21

Independent claim 21 recites:

A femoral component for a total knee joint replacement comprising,
a plurality of segments, each of said segments having a femoral fixation surface adapted to be positioned on a distal end of a femur and at least one assembly surface adapted to be joined to an assembly surface of an adjacent one of said segments said assembly surface being generally planar and arranged to be oriented generally in a plane extending in a proximal-distal direction and in an anterior-posterior direction when said femoral fixation surface is positioned on said distal end of said femur,

wherein at least two adjacent segments each comprise a bearing surface on an anterior portion of said component, said assembly surfaces of said segments being in mutual contact and said bearing surfaces of said adjacent segments being positioned to form a generally continuous bearing surface on an anterior portion of said component,

wherein edges of said mutually contacting assembly surfaces are recessed below said generally continuous bearing surface on an anterior portion of said component. [Emphasis added.]

Timoteo does not teach or suggest such a femoral component. For reasons similar to those expressed above in regard to claim 23, Timoteo does not teach or suggest a plurality of segments that each have “a femoral fixation surface adapted to be positioned on a distal end of a femur and at least one assembly surface adapted to be joined to an assembly surface of an adjacent one of said segments.”

Moreover, the condyles 2, 3, 9 of Timoteo do not form a generally continuous bearing surface on an anterior portion of the component. As shown in Timoteo, condyles 2, 3, 9 and their respective bearing surfaces are located in the posterior region of the femoral component of Timoteo. Therefore, condyles 2, 3, 9 of Timoteo cannot form a generally continuous gearing surface on an anterior portion of a femoral component.

Dependent claim 22 depends from independent claim 21. Consequently, it is patentable over Timoteo for at least the same reasons as claim 21.

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance.

Respectfully submitted,

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